

Not Relevant

From: Steven Callen <steven.callen@bayer.com>

Sent: Tuesday, March 8, 2022 4:57 PM

To: Schmid, Emily <Schmid.Emily@epa.gov>

Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>;
Meadows, Sarah <Meadows.Sarah@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>;
BCSReg_Archive <esepamailbox@bayer.com>

Subject: RE: XtendiMax Supplemental Labels

Hi Emily,

The team just finished with updating these amended labels. Thanks for your patience! Please let us know if you have any questions.

All the best,
Steven

From: Steven Callen

Sent: Thursday, March 3, 2022 5:29 PM

To: Schmid, Emily <Schmid.Emily@epa.gov>

Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>;
BCSReg_Archive <esepamailbox@bayer.com>; Meadows, Sarah <Meadows.Sarah@epa.gov>;
Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>

Subject: RE: XtendiMax Supplemental Labels

Thanks, Emily.

Perhaps we can discuss tomorrow, but I have two questions about the revised labeling. For the "264-1210 state supp" file, the deletion of the MOA box and AI statement was not deleted like they were on the MN and IA ones. Was this intentional or should we delete those items like those others?

Second, in terms of the instruction to "Revise as an appendix to the master label," do you have any details on what that should look like or will the edits that were made on the labeling bring them inline with this? Perhaps instead of places where we indicated they were supplemental labels we should instead write "Appendix [x]"?

Thanks,
Steven

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Thursday, March 3, 2022 4:21 PM
To: Steven Callen <steven.callen@bayer.com>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>;
BCSReg_Archive <esepamailbox@bayer.com>; Meadows, Sarah <Meadows.Sarah@epa.gov>;
Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: RE: XtendiMax Supplemental Labels

Hi Steven,

Yes, Eastern. Sorry, I should have mentioned that. It's fine for them to attend as well. I just sent an invitation to you that you can forward to the others. Thank you for your flexibility to meet with us so quickly.

Best regards,
Emily

From: Steven Callen <steven.callen@bayer.com>
Sent: Thursday, March 3, 2022 4:30 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>;
BCSReg_Archive <esepamailbox@bayer.com>; Meadows, Sarah <Meadows.Sarah@epa.gov>;
Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: Re: XtendiMax Supplemental Labels

Hi Emily,

Thanks for these. I'll take a look and pass to the Bayer team as well.

Is the time you gave Eastern? If so, that fits my schedule. Is the meeting limited to a few from each registrant? I would imagine George may want to attend, as well as Tom Marvin and maybe one or two others, depending on their schedules.

Thanks,
Steven

On Mar 3, 2022, at 3:15 PM, Schmid, Emily <Schmid.Emily@epa.gov> wrote:

Hi Steven,

Thanks again for your patience and willingness to work quickly with us.

After talking about this internally, we have moved away from the new restrictions being distributed as supplemental labels because it doesn't seem to be appropriate in this case. Usually, supplementals are used for changes that the Agency doesn't feel urgency for it to be integrated into the master label (for example a new use on carrots). Since these restrictions need to be part of the labeling for the 2022 use season, we are asking that they be appendices instead of supplemental labels. Attached you'll find PDFs with our comments. One noteworthy change would be that we asking to change the requirement to check the website from 30 days before use to 7 days.

If possible, we would like to meet with all three registrants together to go over the conditions of registration. If you are amenable to that, are you be available to meet tomorrow (Friday) from 11:00-12:00 to discuss?

Best regards,
Emily

From: Steven Callen <steven.callen@bayer.com>
Sent: Tuesday, March 1, 2022 3:16 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>; Meadows, Sarah <Meadows.Sarah@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: XtendiMax Supplemental Labels

Hi Emily,

Thanks for keeping me posted on this and your anticipated timing. I'll do my best to position our team to act as soon as possible on the label comments. We have also been working on getting the website ready for these supplemental labels and that should be ready to go after the labels are approved.

All the best,
Steven

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Tuesday, March 1, 2022 2:09 PM
To: Steven Callen <steven.callen@bayer.com>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>; Meadows, Sarah <Meadows.Sarah@epa.gov>
Subject: RE: XtendiMax Supplemental Labels

Hi Steven,

Thanks again for submitting the labels. We are still having some internal discussions but hope to get label comments to you tomorrow. If you could be ready to turn them around quickly, that would be really helpful. Additionally, we expect to be in touch to discuss the terms of registration within the next couple of days. We really appreciate your patience.

Best regards,
Emily

From: Steven Callen <steven.callen@bayer.com>
Sent: Thursday, February 24, 2022 1:07 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>; Meadows, Sarah <Meadows.Sarah@epa.gov>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: XtendiMax Supplemental Labels

Hi Emily,

Good timing! The team just finished updating the ML and SL. I have attached them here, along with the draft cover letter I am planning on submitting when these go through CDX later today. Please note that Bayer is proposing for the ML and SL slightly different language for the reference to the additional restrictions and a change to the timing requirement for an applicator to view ESA Bulletins from Bulletins Live! Two.

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Kind regards,
Steven

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Thursday, February 24, 2022 11:00 AM
To: Steven Callen <steven.callen@bayer.com>; Meadows, Sarah <Meadows.Sarah@epa.gov>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay

<Roe.Lindsay@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>;
BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive
<esepamailbox@bayer.com>

Subject: RE: XtendiMax Supplemental Labels

Hi Steven,

Thanks for the update. Do you know when we can expect the labels today?

Best regards,
Emily

From: Steven Callen <steven.callen@bayer.com>

Sent: Wednesday, February 23, 2022 6:17 PM

To: Schmid, Emily <Schmid.Emily@epa.gov>; Meadows, Sarah
<Meadows.Sarah@epa.gov>

Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay
<Roe.Lindsay@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>;
BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive
<esepamailbox@bayer.com>

Subject: RE: XtendiMax Supplemental Labels

Thanks, Emily.

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I have already alerted the team regarding the need for the website, so I will be sure to follow up with them on this. It is helpful to understand your timing so that I can light a fire under them to get to it!

Thanks!
Steven

From: Schmid, Emily <Schmid.Emily@epa.gov>

Sent: Wednesday, February 23, 2022 5:11 PM

To: Steven Callen <steven.callen@bayer.com>; Meadows, Sarah
<Meadows.Sarah@epa.gov>

Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay
<Roe.Lindsay@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>;
BCSReg_Archive <esepamailbox@bayer.com>

Subject: RE: XtendiMax Supplemental Labels

Hi Steven,

Thank you for sending those and for giving us a heads up for the others.

Not Part of Administrative Record
Not Part of Administrative Record and our goal is to be done by next Wednesday. In light of that, the website referenced on the labels will need to be up by Wednesday, or sooner if possible.

If you have any questions or concerns, please feel free to reach out.

Thanks again,
Emily

From: Steven Callen <steven.callen@bayer.com>
Sent: Wednesday, February 23, 2022 4:58 PM
To: Meadows, Sarah <Meadows.Sarah@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: XtendiMax Supplemental Labels

Hi Sarah and Emily,

We have completed the updates for the two state supplemental labels for MN and IA, and those are attached. We should have addressed all of the comments that were made, but please let me know if you see any additional changes that are needed for these two labels.

We are now finalizing the edits on the ML and the new supplemental, which should be available to send to you by tomorrow.

Not Part of Administrative Record
Not Part of Administrative Record
Not Part of Administrative Record All three of these labels will be submitted through CDX, but I will also send courtesy copies to you when they are ready.

Thanks,
Steven

From: Meadows, Sarah <Meadows.Sarah@epa.gov>
Sent: Wednesday, February 23, 2022 9:27 AM
To: Schmid, Emily <Schmid.Emily@epa.gov>; Steven Callen <steven.callen@bayer.com>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: XtendiMax Supplemental Labels

Hi, Steven. I'm just checking in on this. Can you give us an update on the revised master and 3 supplemental labels we're expecting from Bayer?

Thanks,

Sarah

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Sunday, February 20, 2022 5:27 PM
To: Steven Callen <steven.callen@bayer.com>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Meadows, Sarah <Meadows.Sarah@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: XtendiMax Supplemental Labels

Hi Steven,

Sorry for the delayed response. I got behind on emails.

Yes, you can send the revised supplementals to me and Sarah via email.

As for the expiration date, we have discussed it further and agree it would be best for the dates to be the same.

Thank you,
Emily

From: Steven Callen <steven.callen@bayer.com>
Sent: Tuesday, February 15, 2022 2:32 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Meadows, Sarah <Meadows.Sarah@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: XtendiMax Supplemental Labels

Thanks, Emily! Nice to hear from you.

This all looks straightforward to me. We should be able to make these changes, update the master label and create an additional supplemental label, and get them to you by the end of the week at the latest. I'll submit the master label and additional supplemental through CDX as indicated, but shall I send the updated state supplemental labels directly back to you?

There was a question about the expiration date. The states reviewed these labels prior

to us submitting to EPA, and they had no issues with aligning the expiration date on these with that of the XtendiMax label itself. I can confirm again with the states, but we would propose keeping the expiration date as is.

Thanks,
Steven

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Tuesday, February 15, 2022 11:25 AM
To: Steven Callen <steven.callen@bayer.com>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Meadows, Sarah <Meadows.Sarah@epa.gov>
Subject: XtendiMax Supplemental Labels

Hi Steven,

I hope you are doing well!

We have reviewed the labels for Minnesota and Iowa and have some comments (PDFs attached).

It has been decided that the best way to get this information out to the user is to have each registrant set up a website that will hold supplemental labels and add a general direction to the master label that says, "You must check [X website] for state specific restrictions within 30 days of application of this product." That way, if there are changes to these supplemental labels, or if other states want to add supplemental labels, the master label won't need to be updated every time. Additionally, we'll need a supplemental label with this direction since some of the product is already in the hands of the users and can't be relabeled with this direction. You can submit both of those as a fast track label amendment.

Most of the comments have to do with these needing to be supplemental labels rather than bulletins, but if you have any questions about our comments or anything else, please feel free to reach out.

Best regards,
Emily

Emily Schmid
Product Manager 25
Herbicide Branch
Registration Division, Office of Pesticide Programs
U.S. Environmental Protection Agency

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